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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/060,765	04/15/98	MEHTA	

N P/546-192

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HM22/0427

EXAMINER	
SCHNIZER, H	
ART UNIT	PAPER NUMBER

1653

*9*

DATE MAILED:

04/27/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/060,765

Applicant(s)  
Mehta et al.

Examiner  
Holly Schnizer

Group Art Unit  
1653



☒ Responsive to communication(s) filed on Nov 9, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-101 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-101 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Election/Restriction*

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1, 2, 5-15, 20, 22-27, 32-38, 40-43, 65-67, 70, 73 drawn to a vector, host cell, and method of making a peptide wherein the protein expressed from the vector is directed to the periplasmic space of the host cell, classified in class 435, subclass 320.1.
  - II. Claims 3 and 4 drawn to a vector, a host cell, and a method of making a peptide wherein expression is controlled by a repressor protein expressed from the vector, classified in class 435, subclass 320.1.
  - III. Claims 16-19, 21, 28-31, 39, 71, and 74 drawn to a vector and a host cell wherein the vector contains nucleic acid which codes for a secretion enhancer, classified in class 435, subclass 320.1.
  - IV. Claims 44-46 and 99-101, drawn to a method of inducing protein expression, classified in class 435, subclass 69.1.
  - V. Claims 47-64, 68, 69, 72, 75, 82-85, 89, and 90 drawn to a method of protein expression which involves inducing expression and controlling cell growth by adding a carbon source, classified in class 435, subclass 69.1.

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- VI. Claims 76-77 and 79-80 drawn to a method of producing a protein including sulfonation of the peptide product during the recovery step, classified in class 530, subclass 408.
- VII. Claims 78 and 81, drawn to a method of producing a protein wherein expression is controlled using a repressor and the recovery step includes sulfonation of the peptide product, classified in class 530, subclass 408.
- VIII. Claims 86-87, 91-94, and 96-97, drawn to a method of producing an amidated peptide product, classified in class 530, subclass 409.
- IX. Claims 88, 95, and 98 drawn to a method of expressing a peptide product which will be excreted from the cell and amidated and wherein expression is induced, classified in class 530, subclass 409.

The inventions are distinct, each from the other because of the following reason:

- 2. The vectors of Groups I, II, and III are directed to separate and distinct inventions. The vectors of Group I contain nucleic acids coding for a peptide product coupled in reading frame with nucleic acids coding for a signal peptide such that the peptide produced using the vector of Group I is directed to the periplasmic space of the cell. The vector of Group II includes all of the components of the vector of Group I however, it also includes additional nucleic acids coding for a repressor peptide such that expression from the vector of Group II can be repressed. The vector of Group II does not include nucleic acid encoding a secretion enhancing protein such as is found in the vector of Group III. The vector of Group III includes all of the components of

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Group I however, it also includes nucleic acid encoding a secretion protein so that the peptide produced using the vector of Group III will be directed to the outside of the cell. The vector of Group III does not contain nucleic acids encoding a repressor peptide such as is found in the vector of Group II. The vectors of Groups I, II, and III have different nucleic acid sequences and encode for different proteins and can be used for different outcomes. These products are capable of separate manufacture, use, or sale as claimed, and are patentable (novel and unobvious) over each other (though they may each be unpatentable because of the prior art).

3. Inventions I-III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the vectors of Groups I, II, and III can be used in methods of making a protein which do not require the step of inducing expression.

4. The vectors of Inventions I-III are related to the methods of Inventions V-IX by virtue of being a vector which can be used to make a protein product. However, the Claims of Inventions V-IX are drawn to steps which occur after the process of making a protein product and the steps are independent of the vectors used. For example, the vectors are not required for or involved in the steps of controlling cell growth by adding a carbon source, sulfonation, or amidation claimed in Inventions VI-IX.

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5. Invention IV is related to Invention V in that both are methods of making a protein which include an induction step. However, Invention V includes an additional step of adding a carbon source to the cell culture which is not included in the method of Invention IV. Therefore, the methods of Invention V and VI are functionally distinct since they require different reagents, different steps, and have different effects. Furthermore, each method requires a non-coextensive search because of the different steps.

6. The method of Groups IV and V are unrelated to the methods of Groups VI and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together or they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of making a protein of Groups IV and V does not include and is independent of the step of sulfonating the protein included in the methods of Groups VI and VII. The methods of Groups IV and V are functionally distinct from the methods of Groups VI and VII since they require different reagents, process steps, and produce distinct products.

7. Invention VI is related to Invention VII in that both are methods of making a protein which include a sulfonation step. However, Invention VII includes an additional step which is not included in Invention VI; the step of adding a carbon source to the cell culture. Therefore, the methods of Invention VII and Invention VI are functionally distinct since they require different reagents, different steps, and have different effects.

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8. The Inventions of Groups VIII and IX are unrelated to the methods of Groups IV-VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together or they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions have different functions and different effects. Inventions VIII and IX are directed to methods of making an amidated peptide product. The methods of Inventions VIII and IX require that the protein expressed have a C-terminal glycine and include a step of amidating the peptide product. Inventions IV-VII are also methods of making a peptide product however, these methods do not require that the protein expressed have a C-terminal glycine and these methods do not include the step of amidating the peptide product. Therefore, these groups represent separate and distinct methods with different starting materials, protocols, and outcomes and they are patentable one over the other.



9. Invention VIII is related to Invention IX by virtue that both share an amidation step. However, Inventions VIII and IX are independent and distinct, each from the other, because the method of Group IX has an additional step of inducing expression which is not included in the method of Invention VIII and therefore would result in a different outcome. Furthermore, each method requires a non-coextensive search because of the different process steps and outcomes.

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8. The Inventions of Groups VIII and IX are unrelated to the methods of Groups IV-VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together or they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions have different functions and different effects. Inventions VIII and IX are directed to methods of making an amidated peptide product. The methods of Inventions VIII and IX require that the protein expressed have a C-terminal glycine and include a step of amidating the peptide product. Inventions IV-VII are also methods of making a peptide product however, these methods do not require that the protein expressed have a C-terminal glycine and these methods do not include the step of amidating the peptide product. Therefore, these groups represent separate and distinct methods with different starting materials, protocols, and outcomes and they are patentable one over the other.
9. Invention VIII is related to Invention IX by virtue that both share an amidation step. However, Inventions VIII and IX are independent and distinct, each from the other, because the method of Group IX has an additional step of inducing expression which is not included in the method of Invention VIII and therefore would result in a different outcome. Furthermore, each method requires a non-coextensive search because of the different process steps and outcomes.
10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.



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11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-3722. The examiner can normally be reached Monday-Friday from 7:30 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bradley Sisson, can be reached at (703) 308-3978. The fax phone number for Official Papers to this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

HS  
Holly Schnizer, Ph.D.  
April 22, 1999

  
KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER